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1           Claim 38 (previously presented) Method for effecting an  
2 immunological response in a living animal host including a human  
3 comprising administering the virus according to claim 20 to the  
4 animal or human to be treated.

1           Claim 39 (previously presented) Method according to  
2 claim 38 comprising the administration of at least  $10^2$  TCID<sub>50</sub>  
3 (tissue culture infectious dose) of the virus.

1           Claim 40 (previously presented) A cell containing the  
2 virus according to claim 20.

1           Claim 41 (previously presented) A method for the  
2 production of a recombinant virus according to claim 20 comprising  
3 the step of inserting at least two expression cassettes into the  
4 genome of a poxvirus.

1           Claim 42 (previously presented) Method for effecting an  
2 immunological response in a living animal host, including a human,  
3 comprising administering the composition or vaccine according to  
4 claim 34 to the animal or human to be treated.

REMARKS

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This amendment is submitted in an earnest effort to bring this application to issue without delay.

Applicants wish to thank Examiners Hurt and Canpell for conducting a telephone interview with the Applicants' undersigned attorneys on 7 May 2007. During the interview the Examiners and the undersigned discussed the Applicants' amendment filed 9 March 2007. The undersigned expressed Applicants' belief that the claims in the response overcame all of the bases for rejection of the claims previously presented under 35 USC 112, first paragraph as based upon a specification that inadequately describes the invention as well as under either 35 USC 102 or as obvious under 35 USC 103 in view of the PICKUP et al reference, alone or in combination with BLANCHARD et al.

The undersigned discussed first of all the definition of the ATI promoter in amended claim 20 and argued that the definition found adequate support in the specification. Examiner Hurt asked the undersigned to specify where Applicants have support in the specification for claim 20, and the undersigned referred her to page 5, line 25 to page 8, line 29. The undersigned also made reference to the case law cited in the amendment of 9 March 2007 indicating that either a list of ultimate species per se or as alternatively as few as one ultimate species together with language identifying a common structural element of all species within a given generic definition of compounds should be adequate to support that generic definition. Both Examiners agreed that independent

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claim 20 as last now presented as well as the claims dependent thereon had adequate support in the specification so that the Examiners had no plans to maintain a rejection of any such claim under 35 USC 112, first paragraph, as based upon a specification that fails to adequately define the invention.

Before the Examiners and the undersigned discussed the rejection of the claims as either anticipated or obvious in view of the cited prior art, the undersigned proposed an alternative independent claim 20 to claim 20 as last presented. Proposed amended claim 20 is slightly broader than claim 20 presented in the application since only nucleotides 25 through 29 from the cowpox ATI promoter are required instead of nucleotides 22 through 29. The Examiners indicated that they believed that proposed amended claim 20 did appear as adequately supported by the specification and so the Examiners indicated that it will not be likely that if Applicants choose to substitute the alternative independent claim 20 for independent claim 20 last presented, the Examiner would reject such a claim under 35 USC 112, first paragraph.

The Examiners made it clear, however, that will have to conduct another search of the prior art to determine whether the claims now presented patentably distinguish over the prior art.

The Examiners then asked us why the claims in the response presented in March patentably distinguish over the cited

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prior art, especially PICKUP et al. The undersigned emphasized once again that Applicants alone prepare a recombinant poxvirus which includes two cowpox ATI promoters and two coding sequences under the control of the respective cowpox ATI promoters, and that there is no disclosure or suggestion in PICKUP of such a recombinant poxvirus. The undersigned again emphasized that surprisingly Applicants can prepare such a recombinant poxvirus and express the coding sequences without the problem of homologous recombination taking place between the two promoters which would interfere with the expression of the coding sequences under the control of the respective promoters.

During the telephone interview the undersigned further distinguished over PICKUP et al by pointing out that the reference discloses in Fig 1 a 5'- cis acting element I upstream of a coding sequence to be expressed and a 3'-cis acting element II downstream of the same coding sequence to be expressed. Only one coding sequence is introduced into the recombinant poxvirus as opposed to two according to the present invention. Furthermore now that Applicants have more sharply defined their cowpox ATI promoters, it is clear that the 3'-cis acting element as shown in Figure 2 bears no structural resemblance to the cowpox ATI promoters as now defined in the present claims. While the 5'-cis acting element does include SEQ ID NO:1, the entire disclosure in PICKUP falls far short as providing any basis for the anticipation or obviousness of the presently claimed invention.

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Nor does combining BLANCHARD et al with PICKUP et al suggest the presently claimed invention and the lack of difficulty with homologous recombination between the two cowpox ATI promoters each controlling separate coding sequences within the recombinant poxvirus. The undersigned referred the Examiners to the HOWLEY et al article that Applicants made of record as part of their last response and indicated that this reference is actually the closest prior art because it shows adding two promoters each controlling respectively a DNA sequence to a poxvirus to form a recombinant poxvirus, and that expression of those sequences was disturbed by homologous recombination between the two promoter regions. The undersigned made it clear that the promoter regions disclosed in the HOWLEY et al reference were not cowpox ATI promoter regions, but instead were p 7.5 promoters. In any even the prior art neither discloses nor suggests the presently claimed invention with its two cowpox ATI promoters controlling respectively two heterologous sequences without any interference from homologous recombination between the two promoters.

Examiner Hurt then asked for confirmation that the Applicants' virus MVA-BN is not a proprietary product of Bavarian Nordic and that the identify of this recombinant poxvirus will not be in doubt in the future. The undersigned stated to the Examiner that MVA-BN is not a proprietary term, but is the common descriptive term known throughout the biotechnology field for this particular recombinant poxvirus. The undersigned also pointed out

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to Examiner Hurt that Applicants' two declarations make it clear that both MVA-BN and MVA-575 have been deposited in a permanent depository in accordance with the requirements of the Budapest Convention and that all restrictions on public access to both MVA-BN and MVA-575 will be lifted upon the issuance of a patent here.

The undersigned also asked the Examiners whether Applicants could reintroduce the claims that the Examiners had previously withdrawn from further consideration as directed to a non-elected invention. Examiner Canpell indicated that Applicants could reinstate those claims provided the claims were of the same scope as claim 20 in terms of the recombinant poxviruses covered. Accordingly Applicants have included in the claims now presented, reinstated claims 36 through 40 and 42, no longer withdrawn from further consideration.

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Applicants believe that all claims now presented are in condition for allowance and a response to that effect is earnestly solicited.

Respectfully submitted,  
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